

Notice of Allowability

Application No.

10/629,817

Examiner

James Balls

Applicant(s)

BEIGHT ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☐ This communication is responsive to ____.
2. ☒ The allowed claim(s) is/are 1 - 13 and 17 - 27.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: ____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date ____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date ____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date ____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date ____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other ____

DETAILED ACTION

Preliminary Matters

1. This application is a divisional of U.S. Application No. 09/857,751, which is the National Stage of International Application No. PCT/US99/29946, filed 15 December 1999, which claims the benefit of U.S. Provisional Application No. 60/113,566, filed 23 December 1998.
3. The Information Disclosure Statement has been considered and a copy of the PTO-1449 is attached hereto.

Examiner's Amendment

4. The following paragraph is amended in accordance with the telephone conversation with Thomas E. Jackson on March 8, 2006. The examiner amended the paragraph beginning at page 1, line 7, of the description to include language underlined below.

This application is a divisional of U.S. Application No. 09/857,751, which is the National Stage of International Application No. PCT/US99/29946, filed 15 December 1999, which claims the benefit of U.S. Provisional Application No. 60/113,556, filed 23 December 1998, all of which are incorporated herein by reference.

Also, Claim 13 was amended to delete the number "1-10," which were present at the end of the claim. The amended claim (upon removal of the "1-10") reads as follows:
"A method of inhibiting factor Xa in a mammal comprising administering to the mammal

in need thereof, and effective amount of a compound of formula I as provided in any of Claims 1-3."

5. Claims 1 – 13 and 17 – 27 are allowable.
6. The Claims have been renumbered as 1 – 24 and rearranged so that all compound claims precede the pharmaceutical formulation claim, which is followed by the process for preparing and method claims.

Reasons for Allowance

7. The following is an examiner's statement of reasons for allowance:

Prior art similar to applicants' claimed invention is disclosed in El-Zanfally, *Condensation of Acetantranil and Phenylantranil with Certain Aminoheterocycles. Attempted Preparation of Some 2,3-Disubstituted 4 (3H)-Quinazolinones*, EGYPT. J. PHARM. SCI., 12(1):29-34 (1976). El-Zanfally provides a hypnotic compound that has a phenyl ring in the Q₂-position instead of a fully saturated piperidine ring. The antithrombotic compound of the present invention requires a piperidine ring in the Q₂-position. There is no teaching in the El-Zanfally reference or other relevant art to motivate a person of ordinary skill to replace the phenyl ring of El-Zanfally's disclosure with a piperidine ring and expect the compound to function as an antithrombotic.

Another prior art reference with a compound similar to applicants' compound is Jensen & Ingvorsen, *Tuberculostatic Derivatives of p-aminobenzoic acid, III. Heterocyclic Derivatives of 4-aminosalicylic acid*, ACTA CHEMICA SCANDINAVICA 6:161-5

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(1952). Jensen & Ingvorsen also disclose a compound that has a phenyl ring in the Q₂-position instead of a fully saturated piperadine ring. Another difference between applicant's compounds and Jensen & Ingvorsen's disclosure is the ring in the Q₁-position. Jensen & Ingvorsen have the Q₁-ring substituted with 4',6'-dimethyl attachments, whereas applicants only allow the 3'-position of the Q₂-ring to be substituted with a methyl, fluoro or chloro substituent. There is no teaching in the Jensen & Ingvorsen reference or other relevant art to motivate a person of ordinary skill to replace the phenyl ring of Jensen & Ingvorsen's disclosure with a piperadine ring and expect the compound to function as an antithrombotic.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Art Not Applied

8. Prior art made of record and not relied upon but considered pertinent to applicant's disclosure is WO200027819. This reference contains a compound similar to applicants' claimed compounds, but was disclosed after applicant's filing date and therefore not applicable to patentability. WO200027819 discloses a growth factor receptor inhibitor that has a pyridine ring in the Q₂-position instead of a saturated piperadine ring.


Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Balls whose telephone number is (571) 272-7997. The examiner can normally be reached on Mon - Fri 8:00am - 4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

R. James Balls
Examiner
Art Unit 1625


Cecelia Tsang
Supervisory Patent Examiner
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